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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,220	07/29/2003	Anton F. J. Fliri	PC10886B	5332

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,220	FLIRI ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 12-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 12-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4,12-32, drawn to compounds,compositions and uses where U=N and A and R variables do not further fuse to form rings, classified in class 544, subclasses such as 295,393;class 514 subclasses 252.14,255.03 .

II. Claims 1-4, 12-32, drawn to compounds,compositions and uses where U=N and A is present to form bridged piperazines and remaining R variables do not further fuse , classified in classes such as 546,548, subclasses various as determined by the nature of the resulting bridged ring system which can vary I size and point of attachment;class 514, various subclasses.

III. Claims 1,3,4, 12-32, drawn to compounds,compositions, and uses where U=C and A and R variables do not further fuse classified in classes such as 546, subclasses such as 234,333;class 544,subclass 335;class 514 subclasses such as 331,357,etc.

IV. Claims 1-4,12-32, drawn to other compounds,compositions,and uses not provided for by I-III above-eg, when U=C and A is present and/or other fused derivatives having varying values of A and U, classified in classes, subclasses as may be determined by actual species described.

Whichever group is elected applicants are further required to elect a single species within that group.

The inventions are distinct, each from the other because of the following reasons: Compounds of groups I-IV relate to compounds of considerable structural dissimilarity in view of the varying and all encompssing choices at R and A variables as well as choices for U which include both saturated and unsaturated rings. Thus they are separately classified and require separate structure searches online. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

In applicants' preliminary response Mr. Bernstein affirmed the election of Group I, the same election made in parent as well as species on p.9, lines 21-22 without traverse. There are no withdrawn claims since claims 5-11 have been

cancelled. Claims which link the various inventions will only be examined with respect to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

The disclosure is objected to because of the following informalities: Status of parent should be updated on p.1 of specification .

Claims 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.There are many instances of duplicate composition claims. See 15 vs 17 vs 19 vs 21. All depend on the same active ingredient and even if they recite different intended uses such is given no material weight in such claims . In re Tuominen 213 USPQ 89. Also note MPEP 2111.02.

2. Method claims 20 and 22 are of indeterminate scope as no particular disorder is ever recited. Such claim language reciting a particular mode of action(s) may read on diseases that are affected by dopamine binding in ways not yet understood. The term "modulating" doesnt even clearly denote a causative factor by which a particular disease may occur. What interaction qualifies as "modulating" and how does one determine a host in need of such? What distinguishes a mammal, the

apparent host, in need of such modulation vs. one who is not in need? D3 receptors recited may be involved in all diseases so how can one be sure that any use of claim's 1 scope does not infringe these claims ? Additionally, determining whether a given disease responds or not to "modulating binding activity at...D3 receptor" would involve much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention **not** what may be discovered by future research as this type of claim language clearly requires.

Claims 1-4,12-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. .

1. Specification is not adequately enabled for the scope of piperazines claimed which can have at either end heteroaromatics having up to 4 nitrogen atoms as well

as heteroaryls both mono- and bicyclic at R9-R19 variables. Only 4 compounds have been made and tested for only D3/D2 receptor binding activity. These contain either pyrimidinyl or phenyl as X-Y-Z ring and phenyl as D-E-F. No other compounds are seen to have been made much less tested for the scope of heteroaryl permitted at R9-R19. Additional compounds described earlier in the specification that are within the claims' scope show a pyridyl as an example of D-E-F ring. Otherwise no adequate representation is seen for such a scope of rings permitted at the several locations discussed above. Receptor binding is known to be structure-sensitive as evidenced at the very least by applicants' own data for compounds much closer in structure to each other than to remaining scope. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a),August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what other

rings,ring systems as heteroaryl (for R9-R19) and D-E-F and X-Y-Z rings might work, this rejection is being applied.

2. The scope of uses within claims 15-22,24,25,27-32 are not adequately enabled based on what is currently known in the art for dopamine receptors in particular D3 receptors relied on herein. Such uses are not considered all treatable based simply on D3 receptor binding as evidenced by Reynolds who discusses potential treatment for psychotic disorders. See 2nd paragraph of p.8, left column. TenBrink on p.46 would also support Parkinson's Disease.

A search in the pertinent art area based on classification of species yielded nothing teaching or suggesting the structural makeup of compounds claimed herein. Thus species embracive within the elected group would be allowed.

Should applicants limit the claims based on the restriction requirement note that claim 2 should be cancelled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600